IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE THE GENERAL CAUSATION TESTIMONY OF KIMBERLY H. ALLISON, M.D.

The Court should exclude the testimony of Plaintiffs' pathology expert Dr. Kimberly H. Allison in its entirety. Dr. Allison may not offer general causation testimony because Plaintiffs refused to allow Defendants Ethicon, Inc., and Johnson & Johnson (collectively, "Ethicon") to take a general causation deposition of Dr. Allison. Plaintiffs asserted that they had not disclosed Dr. Allison as a general causation expert and on this basis made her available for specific causation depositions only. Allowing Dr. Allison to offer general causation testimony now would violate the Court's procedural orders and the parties' agreement, to the unfair prejudice of Ethicon. The cases to which this motion applies are identified in Ex. A to this motion.

To the extent that Dr. Allison formulated general causation opinions, they are unreliable in any event. She cannot base her opinions solely on her clinical experience as the conclusions she reaches here are not conclusions she draws in her pathology practice. She cannot base her opinions on her review of litigation-related pathology specimens because the Court has repeatedly ruled that opinions based on litigation inspired samples, hand-picked by Plaintiffs' counsel, are not derived from the scientific method. She admits that she cannot identify any

support in the scientific literature that establishes a causal connection between the polypropylene degradation she believes she has observed and the clinical symptoms Plaintiffs allege. She not only failed to consider that the purported degradation can be caused by xylene, a common solvent used in tissue processing, rather than degradation *in vivo*, she is ignorant of this known effect. She attributes pain to small entrapped nerves, but admits that it is impossible for her to tell if the nerves are sensory nerves—*i.e.*, nerves that are capable of registering pain. These failings render any general causation opinion Dr. Allison would offer unreliable under Federal Rule of Evidence 702 ("Rule 702") and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

The Court should also preclude Dr. Allison from offering specific causation testimony. She may only offer such testimony if it is based on the required foundational predicate of a general causation opinion — without that basis, an expert's specific causation testimony is irrelevant. Dr. Allison may not offer her own general causation testimony for the reasons explained above. And she has not identified any other expert on whose general causation testimony she relies. In fact, she has not read the expert reports of any of Plaintiffs' experts. Accordingly, the Court should exclude Dr. Allison's specific causation testimony as irrelevant.

For these reasons, Ethicon moves the Court to exclude Dr. Allison's proposed testimony in its entirety.

ARGUMENT

I. Legal Standard.

Ethicon incorporates by reference the standard of review for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

II. Dr. Allison Is Precluded from Offering General Causation Testimony Due to Plaintiffs' Refusal to Present Her for a General Causation Deposition.

Dr. Allison's report includes a section entitled "General Opinions," in which she discusses her views regarding the potential for implanted vaginal polypropylene mesh to cause adverse medical outcomes such as chronic pain, dyspareunia, and mesh erosion. *See* Ex. B, Rule 26 Expert Report of Kimberly H. Allison, M.D. ("Allison Report"), at 3–5. In light of the inclusion of these general-causation-related opinions, Defendants noticed one three-hour "General" deposition and five two-hour case-specific depositions for Dr. Allison, consistent with the agreement of the parties and the procedures established by the Court in this MDL. *See* Ex. D, Am. Notice of Dep. of Kimberly H. Allison, at 1–2.[1] Plaintiffs responded that they had not disclosed Dr. Allison as a general expert in the Wave 1 cases and therefore would not make her available for a three-hour general deposition, only for two-hour case-specific depositions—a position Plaintiffs' counsel repeated on the record at Dr. Allison's depositions. *See, e.g.*, Ex. E, Allison 3/17/16 *Thompson* Dep. Tr. 5:15–6:5. In light of Plaintiffs' refusal to offer Dr. Allison for a general causation deposition, the Court should preclude Dr. Allison from offering general causation testimony in the Wave 1 cases.

III. Dr. Allison's General Causation Testimony Is Unreliable.

Even if the Court were to entertain the possibility of allowing Dr. Allison to offer testimony on general causation—a ruling that would be unjustified in light of Plaintiffs' refusal to allow her to be deposed on those topics—Dr. Allison's opinions would be inadmissible as they are unreliable under *Daubert*. Dr. Allison asserts (1) that polypropylene degrades *in vivo*; (2) this

[1] The case-specific depositions were for each of the cases in which Dr. Allison had been disclosed as a specific-causation expert by Plaintiffs represented by the firm of Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.—namely, the cases of Plaintiffs Daphne Barker, Debbie Joplin, Patti Phelps, Maria Quijano, Lisa Thompson. Plaintiffs' counsel withdrew Dr. Allison as a case-specific expert in *Joplin* and *Quijano* on the morning of Dr. Allison's March 17, 2016 deposition.

degradation can be observed microscopically in pathology samples as a "tree-barking" effect; (3) this degradation causes chronic inflammation, which in turn "can cause a dense plate of scar tissue" to form; (4) "the scarring and chronic inflammation cause stiffening (or hardening) and contracture of the area containing the mesh;" (5) "nerves are frequently entrapped by the fibrosis and tissue ingrowth between and around mesh pores;" and (6) these processes "cause or contribute to complications" that "are the sequelae of the tissue response to the non-inert and degrading mesh with resultant chronic inflammation and scarring."[2] Ex. B, Allison Report, at 3–4. These opinions fail to meet the reliability standard of Rule 702 for five reasons.

First, Dr. Allison cannot rely on her clinical practice to support her opinions that mesh degradation can cause clinical symptoms, as the question she is answering in the mesh litigation is not a question that she answers in her pathology practice. *Second*, Dr. Allison cannot rely on her litigation-related pathology reviews because the hand-picked sample of specimens provided to her by Plaintiffs' counsel are not a statistically-valid, representative sample from which a scientist could conclude that the tree-barking effect caused clinically significant symptoms. *Third*, Dr. Allison's opinions are not supported by the scientific literature because she admits that none of the references in her reliance list support her opinion that *in vivo* mesh degradation causes clinical sequelae. *Fourth*, Dr. Allison has not accounted for other possible explanations for the tree-barking effect she has observed. And *fifth*, Dr. Allison admitted that it is impossible to tell whether the entrapped nerves she observed are sensory—*i.e.*, pain-registering—nerves, rather than motor or autonomic nerves.

[2] "Sequelae" are the aftereffects, or secondary results, of a disease, condition, or injury.

A. Dr. Allison's Clinical Experience Does Not Support Her Conclusion Linking Degradation to Clinical Symptoms.

Dr. Allison is an Associate Professor of Pathology at Stanford University Medical Center. Ex. B, Allison Report, at 2. While Dr. Allison claims to focus on gynecologic pathology in her clinical work, she admits that, since coming to Stanford in January of 2013 she has never reviewed or "signed out" gynecologic pathology. Ex. E, Allison 3/17/16 *Thompson* Dep. Tr. 24:10–12. Gynecologic pathology at Stanford is not reviewed by Dr. Allison, but by Defendants' pathology expert, Dr. Teri Longacre, who is a Professor of Pathology and, among other positions, the Director of Gynecologic Pathology at Stanford. Ex. H, Longacre Report, at 1.

Before coming to Stanford, Dr. Allison spent roughly twelve years at the University of Washington. *See* Ex. C, Allison C.V., at 1–2. Over the course of that decade, she reviewed some ten to twenty mesh explants. Ex. E, Allison 3/17/16 *Thompson* Dep. Tr. 38:8–13.[3] She has no idea if those explants were from women who had complained of pain versus women who had the mesh removed for some reason unrelated to pelvic pain. *Id*. at 39:12–22. Nor is she aware if any of those explants were mesh from a TVT product. *Id*. at 25:18–26:2. She did not conclude in any of those cases, nor has she ever concluded in her pathology practice, that a mesh implant had caused a patient's clinical sequelae:

> Q. Does any physician at Stanford rely upon you to diagnose clinical sequelae from explanted midurethral meshes?
>
> A. No, not currently.
>
> Q. Has any surgeon relied upon you to diagnose the cause of sequelae from explanted midurethral meshes?

[3] Dr. Allison has also reviewed mesh explants provided to her by Plaintiffs' counsel. As explained below, reviews of this non-statistical sample, hand-selected by Plaintiffs, does not provide reliable support for Dr. Allison's opinions.

> A. No, the surgeons are removing them because they have made their own clinical judgment that they need to be removed because [of] the symptoms they are causing.

Ex. G, Allison 3/18/16 *Barker* Dep. Tr. 59:3–59:13.

This admission is consistent with the general principles of what pathologists do—versus what they do not do—in clinical practice. As Dr. Allison acknowledges, the pathologist's role is typically to review a biopsy of a mass and explain to the clinician what the mass is, or, in the context of removal of a foreign material, to document for the surgeon what was removed. Ex. E, Allison 3/17/16 *Thompson* Dep. Tr. 38:15–39:7. As Dr. Allison testified, "It's not the same question as is being asked of me here, in these cases;" in which she is being asked to "link[] the pathology with the clinical symptoms." *Id*. at 39:8–10. And not only has no one ever asked Dr. Allison to do that in a mesh case in her clinical practice, she does not think anyone has ever asked *any* pathologist to do that outside the context of litigation: "Q. Has any urologist, gynecological surgeon at Stanford come down to your office with a vaginal slide after a mesh excision and asked you to correlate any symptom with what you found on the slide? A. No. And I doubt any pathologist has had that occur." *Id*. at 84:21–85:2.

Pathologists are trained to identify tissue response to a foreign body, including acute and chronic inflammation. *See*, *e.g.*, Ex. H, Expert Report of Teri Longacre, M.D. ("Longacre Report"), at 2–3. But a pathologist cannot look at a mesh explant from a patient with clinical symptoms such as pelvic pain and conclude, based on the histology alone, that the mesh is the cause of those symptoms. As acknowledged by Dr. Longacre, such a conclusion would have to be supported by "compelling data that document significant histologic findings in mesh explants from patients with symptoms (pain, exposure, voiding dysfunction, etc.) versus mesh explants from patients who are entirely asymptomatic." *Id*. at 4. Consistent with this view, when Dr. Allison was asked if she had been taught in her pathology training that a pathologist can look at

tissue on a slide and correlate it with clinical symptoms of pain (outside of the context of reviewing neoplastic, or cancerous, tissue), she could only provide limited examples that are not analogous to what Plaintiffs have asked her to do here. Ex. E, Allison 3/17/16 *Thompson* Dep. Tr. 60:5–61:12 (describing the correlation of bone pain with a pathological diagnosis of cancer, Paget's disease, or osteomalacia; the correlation of labor pain with the condition of the placenta being too deeply embedded in the uterus; and the correlation of pain with a pathological diagnosis of endometriosis).

For these reasons, Dr. Allison's clinical experience does not offer meaningful support for her opinions that the inflammation and supposed degradation that she is seeing in her review of the pathology is the cause of the clinical symptoms alleged by Plaintiffs. She must support her conclusions with some scientifically-valid data establishing this causal connection. As explained below, her admissions establish that she cannot do this, rendering her opinions unreliable.

B. Dr. Allison's Review of Pathology Provided by Plaintiffs' Counsel Is Not a Scientifically Valid Basis for Her Opinions.

Like many other of Plaintiffs' experts, Dr. Allison has reviewed mesh explants provided to her by counsel for mesh litigation plaintiffs. She cannot account for how the sample of pathology specimens was chosen, so her review of them was not derived using scientific methods.

As the Court has previously held, Plaintiffs' experts' failure to account for how the pathology samples they received from Plaintiffs' counsel were chosen or prepared for examination renders their opinions derived from review of the samples inadmissible. *See, e.g.*, *Tyree*, 2014 WL 5486694, at *41. In *Tyree*, the Court excluded Dr. Iakovlev's general causation opinions derived from his review of samples provided by plaintiffs' lawyers because he "had no way of knowing what methodology the plaintiffs' lawyers employed in providing him with the

number of meshes they did." *Id*. Dr. Iakovlev gave "no explanation as to whether [his] is a representative sample size or how he chose the particular explants analyzed." *Id*. The Court concluded that it accordingly had "no information as to the 'potential rate of error' inherent in [his] observations" and excluded Dr. Iakovlev's opinions on the grounds that they were not derived using scientific methods. *Id*. (citing, *inter alia*, *Daubert*, 509 U.S. at 594).

The same is true here. Dr. Allison testified that, in addition to the ten to twenty mesh explants she reviewed in her pathology practice, she has reviewed specimens received from mesh litigation plaintiffs' counsel. Ex. K, Allison 10/30/14 *In re C.R. Bard* Dep. Tr. 74:2–23; *see also id*. at 72:3–10 (she reviewed approximately 60 of the 90 specimens sent); Ex. E, Allison 3/17/16 *Thompson* Dep. Tr. 39:24–40:4 (reviewed between 60 and 90 specimens). All were from patients who complained of pain and/or erosion—there was no control of any kind. *Id*. at 40:6–17; Ex. K, Allison 10/30/14 *In re C.R. Bard* Dep. Tr. 73:18–22. She does not know how they were selected or processed. *Id*. 74:12–14. She therefore cannot provide any information regarding the determination of the sample size, the methodology employed in selecting the samples, or the potential rate of error inherent in her observations. *Tyree*, 2014 WL 5486694, at *41. The Court should adopt its previous rulings here and exclude Dr. Allison's opinions based on her review of the pathology provided by Plaintiffs as unreliable under Rule 702 and *Daubert*.

C. The Admissions of Dr. Allison and Other Plaintiff Experts Establish that Her Degradation Opinions Are Unreliable.

Dr. Allison's opinions are unreliable because they are not "based upon sufficient facts or data" as required by Rule 702. *Edwards*, 2014 WL 3361923, at *1. Because they do not "rest[] on a reliable foundation, the Court should exclude them in their entirety. *Id*. Dr. Allison testified that, in forming her opinion that the purported degradation she observed can cause clinical symptoms, she relied on Dr. Iakovlev's publications describing mesh degradation. Ex. F, Allison

3/17/16 *Phelps* Dep. Tr. 34:18–35:5. She then "linked" this purported degradation, which she believes she has observed in the pathology samples Plaintiffs' counsel have provided her, "as all related to the clinical symptoms" alleged by Plaintiffs. *Id*. at 86:1–10. Yet Dr. Allison has not supported this hypothesized link with any valid scientific evidence.

Dr. Allison has no valid evidence that the fibrosis and inflammation she has observed in mesh explants provided to her by Plaintiffs' counsel is different from—let alone worse than—the fibrosis and inflammation in patients who have not experienced adverse clinical symptoms after mesh implantation. She admitted that the degree of fibrosis and inflammation she attributed to mesh degradation "hasn't been systematically linked to patients with pain versus patients without pain or patients with [mesh] exposure versus patients without exposure." Ex. E, Allison 3/17/16 *Thompson* Dep. Tr. 36:17–21. Dr. Allison also testified that she observed scarring of skeletal muscle that she believed to be significant, stating, "I have seen cases where skeletal muscle is scarred and fibrosed and in the surrounding tissue with mesh kind of embedded within it, and I think that that's damaging the tissue in that anatomic location." *Id*. at 58:22–59:1. Yet she admitted that she does not know what tissue would look like in a woman suffering from pelvic laxity who did not have mesh, as she does not get those kinds of specimens. Ex. F, Allison 3/17/16 *Phelps* Dep. Tr. 37:20–25.

In fact, when asked to identify any randomized controlled study comparing tissues surrounding midurethral slings in women who did not complain of pain versus women who did complain of pain, the only study she could identify was the 2015 Hill Study. Ex. G, Allison 3/18/16 *Barker* Dep. Tr. 30:20–31:18; s*ee also* Hill, JA et al., Histopathology of excised midurethral sling mesh, Int Urogynecol J (2015) 26:591–595, attached as Ex. I. But this study refutes Dr. Allison's opinions. The authors concluded that midurethral sling explants removed

for reasons other than pain showed *more* inflammation than those removed for pain and/or mesh exposure. *Id*. at 32:14–19. And they noted further, "The vaginal tissue fibrosis and giant cell reaction are similar in patients who undergo mesh excision for voiding dysfunction and pain and/or mesh exposure." *Id*. at 32:21–24. The only criticism of the study that Dr. Allison could muster was that there was "no control group of patients with absolutely no symptoms," (*id*. at 32:25–33:6)—an impossibility, as, in the words of Plaintiffs' urogynecology expert Dr. Ostergard, "no Human Subjects Committee would approve" a study that required explantation of vaginal mesh from asymptomatic patients. Ex. J, Ostergard 3/9/16 Dep. Tr. 101:5–17.

With respect to degradation, Dr. Allison admits that none of the scientific literature on which she relied establishes that *in vivo* mesh degradation causes clinical symptoms:

> Q. Can you circle for me or highlight on that exhibit the literature that proves to a reasonable degree of medical certainty that there is clinical sequelae in vivo from in vivo degradation? . . .
>
> THE WITNESS: No.

Ex. F, Allison 3/17/16 *Phelps* Dep. 78:8–13; *see also id.* at 86:12–17 (Q. . . . Are you stating under oath that the references that you've said [are] in your report marked as Exhibit 2 are medical literature that proves that there [are] clinical sequelae to the degradation of mesh in vivo? A. No."); Ex. G, Allison 3/18/16 *Barker* Dep. Tr. 28:15–20 ("Q. Can you point to anything in Exhibit 4 that is a randomized trial or trial that has a control that links a specific clinical symptom of pain to what can be seen on a pathology slide of vaginal tissue that contains mesh? A. No."). This is consistent with Dr. Ostergard's admission that he cannot make any link at all between the alleged degradation of polypropylene and Plaintiffs' injuries. Dr. Ostergard readily admitted that "[a]t this point in time, we cannot specifically relate degradation to complications in patients. . . ." Ex. J, Ostergard 3/9/16 Dep. Tr. 102:12–14. Similarly, when asked if the clinical manifestation of the alleged degradation would be variable across patients, Dr. Ostergard

responded, "Well, since we don't know what the manifestations are, it's very difficult to answer that question." *Id*. at 144:10–16.

Dr. Allison cannot identify any valid scientific evidence to support her opinions that degradation occurs *in vivo* and causes inflammation and fibrosis that results in clinically significant symptoms. Her testimony is therefore unreliable. The Court should exclude it under Rule 702 and *Daubert*.

D. Dr. Allison Did Not Address Literature and Opinions that Do Not Support Her Conclusions About Mesh Degradation.

Dr. Allison's attribution of the tree-barking effect she observed in pathology specimens provided by plaintiffs' counsel to degradation of the mesh is unreliable. She has not considered the possibility that the effect may be the result of tissue processing with a commonly-used solvent, xylene, which is widely known to degrade polypropylene.

"An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'" *Tyree v. Boston Sci. Corp*., 54 F. Supp. 3d 501, 520 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014) (citing *In re Rezulin Prods. Liab. Litig*., 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005)). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.* (citing, *inter alia*, *Rezulin*, 369 F. Supp. 2d at 425).

Dr. Allison is aware that xylene is used in tissue processing. Ex. G, Allison 3/18/16 *Barker* Dep. Tr. 52:9–13. And it is well known that xylene dissolves polypropylene. *See, e.g.*, 21 C.F.R. § 177.1520(d)(4) (describing analytical methods for testing the purity of olefin polymers including polypropylene by dissolving them in xylene); Ex. M, 1978 National Institute for Occupational Safety and Health Occupational Health Guideline for Xylene, at 2 ("Reactivity . . .

Special precautions: Xylene will attack some forms of plastics"). As Dr. Longacre explained, during the "processing of mesh explant material for preparation of histologic slides, the mesh is exposed to formalin, varying thermal conditions, and solvents, including xylene," which "alters the histologic staining and refractile properties of the mesh material in a similar manner to that which has been attributed to in vivo degradation." Ex. H, Longacre Report, at 10. Dr. Allison reviewed Dr. Longacre's report in its entirety and identified every statement with which she did not agree; she did not dispute this statement. *See* Ex. E, Allison 3/17/16 *Thompson* Dep. 64:10–21.

Yet Dr. Allison did not consider or account for the possibility that the tree-barking she describes is the result of processing with xylene rather than degradation of the mesh *in vivo*. *See generally* Ex. B, Allison Report. In fact, she had no idea what xylene does to polypropylene, or if the samples about which she was testifying had been processed with xylene. Ex. G, Allison 3/18/16 *Barker* Dep. Tr. 52:14–20. Dr. Iakovlev has testified that fully saturating mesh explant tissue with xylene is part of the standard procedure for processing the tissue for the preparation of histologic slides—a procedure he follows. Ex. N, 3/18/14 Iakovlev Dep. Tr. 198:21–199:23. It is therefore likely that samples reviewed by Dr. Allison, as well as specimens presented in the literature on which she relied, were processed with xylene.

Dr. Allison's failure to address this well-known effect of xylene on polypropylene, and the likelihood that samples she reviewed and samples discussed in the literature on which she relied were exposed to xylene, renders her degradation-related opinions unreliable. The Court should exclude her testimony regarding tree-barking and all of her opinions derived therefrom.

E. Dr. Allison's Opinion that Entrapped Nerves that She Has Observed Cause Pain Is Unreliable.

Dr. Allison opines that "the integration of nerve fibers into the scarring around these mesh fibers more likely than not contributes to the pain in these patients, and would emphasize that there are plenty of sensory nerves in that area that it is likely to affect." Ex. G, Allison 3/17/16 *Thompson* Dep. Tr. 48:18–23. Dr. Allison has no scientific basis for this opinion. It is therefore unreliable and her testimony on this point should be excluded in its entirety. *See, e.g.*, *Edwards*, 2014 WL 3361923, at *1.

Dr. Allison reviewed the expert report of Ethicon's expert Dr. Hannes Vogel, a Professor of Neuropathology and the Director of Neuropathology at Stanford, and testified that she agreed with essentially everything in his report.[4] She agrees, as she must, that only sensory nerves—versus motor or autonomic nerves—convey sensations of pain. Ex. L, Vogel Report, at 4; Ex. G, Allison 3/18/16 *Barker* Dep. Tr. 17:3–18:1 (agreeing with Vogel Report through page 7). She agrees with Dr. Vogel that "[t]here is no precedent for the diagnosis of intrinsic diseases of peripheral nerves by examining nerve twigs that are found incidentally in surgically excised tissues, regardless of the presence of other microscopic findings in such tissues." Ex. L, Vogel Report, at 4. She agrees that "[t]he majority of the innervation [in the pelvic floor] is autonomic." *Id*. at 7. And she admits that it is impossible for her to determine if the nerves she observed to be integrated in the tissue in and around the mesh are sensory nerves:

> Q. . . . I want you to turn to page 6 of Dr. Vogel's report. And again, you don't dispute that he's an expert in the field of neuropathology, do you?

[4] Ex. G, Allison 3/18/16 *Barker* Dep. Tr. 17:3–18:1 (agrees with everything up to "Response to Plaintiff's Expert" at page 7); *id*. at 18:25–20:9 (no disagreement with pages 7 to 9); *id*. at 21:2–22:12 (no disagreement with pages 9 to 13); *id*. at 22:13–23:15 (only disagreement with pages 13 to 15 is with respect to statement that Dr. Iakovlev makes an "erroneous link between fibrosis and/or inflammation with pain in a small percentage of patients having undergone mesh explantation;" she would omit "erroneous"); *see also* Ex. L, Expert Report of Hannes Vogel, M.D. ("Vogel Report").

> A. Of course not.
>
> Q. All right. Page 6, fourth line down, can you read that—that sentence that starts with pathologists and then has a dash?
>
> A. "Pathologists—even those trained and experienced in neuropathology such as myself—are not able to examine a histology section under the light microscope and determine whether nerve twigs in the field are sensory, motor or autonomic in nature. . . . Stains such as immunohistochemistry for S100 and neurofilament, which can aid in the identification of parts of nerves, specifically Schwann cells and axons respectfully, are incapable of differentiating between sensory, motor and autonomic nerves. Moreover, S100 and neurofilament do not identify sensory receptors."
>
> Q. Do you disagree with those sentences?
>
> A. No.

Ex. E, Allison 3/17/16 *Thompson* Dep. Tr. 57:12–58:11; *see also* Ex. F, Allison 3/17/16 *Phelps* Dep. Tr. 45:23–46:2 ("Q. And you agree with Dr. Vogel's . . . report, that using an S100 stain, you're not able to tell whether those nerves are sensory, correct? A. Correct."); Ex. G, Allison 3/18/16 *Barker* Dep. Tr. 45:23–25 (reviewing Ms. Barker's pathology, "Q. And you have no idea whether those nerves are motor or sensory, do you? A. No."); Ex. L, Vogel Report, at 5 ("[T]he extent to which a peripheral nerve transmits pain cannot be determined by its microscopic appearance. Even if a nerve fiber is sensory, the type of sensation it carries cannot be determined without identification of the sensory receptor that creates the signal or an understanding of where the nerve projections synapse in the spinal cord.").

Yet when asked if she had an opinion to a reasonable degree of medical certainty that some of the nerves on Ms. Barker's photomicrographs are motor or sensory, she testified,

> A. Some of them are likely—more likely than not sensory.
>
> Q. Which ones?
>
> A. I cannot point to—you cannot tell under histology which ones are. That's not something we can do.

Q. What type of sensory-invoking nerves are these?

A. I don't know.

Ex. G, Allison 3/18/16 *Barker* Dep. Tr. 48:15–49:1.

Dr. Allison admits that it is impossible for her to determine whether the nerves integrated in the tissue she has observed under the light microscope are nerves that are capable of producing sensations of pain. She nonetheless purports to conclude, to a reasonable degree of medical certainty, that some of them are more likely than not sensory nerves. This is inadmissible *ipse dixit*. *See, e.g.*, *Tyree*, 54 F. Supp. 3d at 543 (citing *Daubert*, 509 U.S. at 594 regarding "the importance of ascertainable 'standards' to govern the expert's methodology in reaching his opinion). The Court should exclude Dr. Allison's opinions that the entrapped nerves she has observed can cause pain in their entirety.

IV. Dr. Allison Is Precluded from Offering Specific Causation Testimony Given Her Failure to Support Her Opinions with General Causation Testimony.

Dr. Allison's proposed testimony on specific causation should also be excluded, "because it lacks a required foundational predicate—a general causation opinion." *In re Mirena IUD Prods. Liab. Litig.*, No. 13-CV-6586 (CS), 2016 WL 890251, at *39 (S.D.N.Y. Mar. 8, 2016). It is well-established that an expert's "failure to offer or rely upon a general causation opinion renders his specific causation opinions without foundation and therefore inadmissible." *Id.*; *see also id.* ("[I]n the absence of evidence of general causation, evidence of specific causation is 'irrelevant.'") (citing *In re Rezulin Prods. Liab. Litig.*, 441 F. Supp. 2d 567, 578 (S.D.N.Y. 2006)). Indeed, this Court recognized and relied upon this well-established rule of law in *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589 (S.D.W. Va. 2013), when it excluded an expert's specific-causation opinions when there was no reliable general-causation predicate. *Id.* at 605. Accordingly, to offer opinion testimony on specific causation, an expert must first "show general

causation or rely on a reliable general causation opinion." *In re Mirena IUD*, 2016 WL 890251, at *39.

In *Mirena*, one of plaintiffs' specific causation experts proposed to testify on specific causation only. *Id*. Defendants moved the court to exclude the expert's proposed testimony for failure to provide the required foundational predicate of a general causation opinion. *Id*. Plaintiffs argued that they intended to rely on other experts for a general causation opinion, but the court rejected this argument. *Id*. The expert "ha[d] not relied on those experts in forming his [specific causation] opinion . . . , nor ha[d] he offered a general causation opinion himself, creating a gap in the causal chain of his analysis." *Id*. (citing *In re Accutane Prods. Liab. Litig*., No. 04–MD–2523, 2007 WL 4404176, at *1 (M.D. Fla. Aug. 15, 2007); *Adams v. Cooper Indus., Inc*., No. 03–CV–476, 2007 WL 2219212, at *8 (E.D. Ky. July 30, 2007); *Colon v. Abbott Labs*., 397 F. Supp. 2d 405, 416 (E.D.N.Y.2005) (internal citations omitted). The court concluded that the expert's "failure to offer or rely upon a general causation opinion renders his specific causation opinions without foundation and therefore inadmissible." *Id*.

The same is true here. Dr. Allison has not offered her own general causation opinions, and is precluded from doing so by Plaintiffs' refusal to disclose her as a general causation expert or offer her for a general causation deposition. *See supra* Section II. To the extent that she purports to have developed her own general causation opinions, they are unreliable. *See supra* Section III. And she has failed to identify any general causation expert on whose proposed testimony she relied in reaching her opinions. Dr. Allison testified that she did not review any reports of any of Plaintiffs' experts; the only reports she read in these cases were those of Defendants' pathology experts Dr. Felix, Dr. Longacre, and Dr. Vogel. *See* Ex. E, Allison 3/17/16 *Thompson* Dep. Tr. 12:22–13:8 (read Dr. Felix's report in *Barker*); *id*. at 13:22–24 (read

Dr. Longacre's report); *id*. at 15:10–14 (did not recall reading any other reports); *supra* n.4 (discussing Dr. Allison's review of Dr. Vogel's report); Ex. G, Allison 3/18/16 *Barker* Dep. Tr. 22:21–23:1 (by Plaintiffs' counsel, "Dr. Allison has neither seen nor relied on Dr. Iakovlev's report in rendering her opinions in this case"); *id*. at 24:13–17 (same); *id*. at 37:8–16 (Dr. Allison did not rely on any of Dr. Iakovlev's expert reports or any of his sworn testimony in reaching her opinions).

Her failure to establish the "foundational predicate" of a general causation opinion to support her proposed testimony on specific causation renders her specific causation testimony "irrelevant." *Mirena*, 2016 WL 890251, at *39. The Court should therefore exclude her specific causation testimony in its entirety.

CONCLUSION

For the reasons stated above, the Court should grant Ethicon's Motion to Exclude the General Causation Testimony of Kimberly H. Allison, M.D., as well as Ethicon's motions to exclude her specific causation testimony in the *Thompson*, *Phelps*, and *Barker* cases, which are incorporated herein.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	

CERTIFICATE OF SERVICE

I certify that on April 20, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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